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TITLE: Composition and method

Abstract Text (1):

A diet which induces a state of ketosis in a canine or feline which comprises an edible composition relatively high in fats and relatively low in carbohydrates.

Brief Summary Text (2):

Diet has been used in an attempt to manage conditions in man for many years. Obesity is often times directly related to the total and type of caloric intake for man over a given period of time. Diabetes first line of control is usually an attempt at management through diet. Similarly an attempt to limit high cholesterol values, hypertension, and urinary stone formation is frequently attempted by diet. In man, it has additionally been observed that a diet, which brings about a state of ketosis, that is increased ketone bodies, has met with some success in controlling the seizures associated with epilepsy.

Brief Summary Text (3):

In lower mammals, such as dogs, experiments to create a state of ketosis through the use of starvation has met with only limited attainment, J. J. de Bruijne, International Journal of Obesity (1979) 3, 239-247, see a further study on prolonged fasting in dogs by J. J. de Bruline, Metabolism (1981) Vol. 30, no. 2, 190-194. No ketotic state has been reported to have been achieved for a dog through use of a designed diet that uses a relatively high fat level combined with a relatively low carbohydrate level. The same lack of information concerning felines and lack of attainment of ketosis through use of diet, complete in all nutrients, is also present.

Brief Summary Text (4):

It has now been discovered that a state of ketosis can be achieved in lower mammals through the use of diet, in general a diet that is relatively high in fat and relatively low in carbohydrates. This alteration of metabolism, ketosis, can be useful in the management of various medical or behavioral conditions including but not limited to seizures, more specifically those related to idiopathic epilepsy; body weight regulation; behavior problems; muscle metabolism; carbohydrate intolerance; disorders of insulin secretion or insulin deficiency; muscle fatigue; suboptimal exercise tolerance and a combination of any of these conditions. In addition, alterations in metabolism and ketosis can enhance exercise performance.

Brief Summary Text (8):

Carbohydrate measured as nitrogen free extract of about Zero to about 20 wt % of the diet, protein of from about 25% to about 70 wt % of the diet, and fat of from about 20 wt % to about 70 wt % of the diet all on a dry matter basis.

Brief Summary Text (10):

Carbohydrate as measured as nitrogen free extract of about zero to about 20 wt % of the diet, protein of from about 25 to about 70 wt % of the diet, and fat of from about 20 to about 70 wt % of the diet, all on a dry matter basis.

Brief Summary Text (11):

A further aspect of the invention is a method of inducing a ketotic state in a dog or cat which comprises feeding the dog or cat a diet which is relatively high in fat and

relatively low in carbohydrate.

Brief Summary Text (12):

A still further aspect of the invention is a method for managing a medical or behavioral condition selected from the group consisting of seizures (related to idiopathic epilepsy), body weight regulation, behavior problems, muscle metabolism, carbohydrate intolerance, disorders of insulin secretion or deficiency, muscle fatigue and suboptimal exercise tolerance; enhanced exercise performance; and, a combination of any of these conditions in a dog or cat in need of such management which comprises feeding the dog or cat a diet which induces ketosis.

Brief Summary Text (14):

A diet that induces a ketotic state in dogs and cats has been found to be high in fats and low in carbohydrates. By a "ketotic state" is meant alteration of the mammal's metabolism so as to increase the quantity of ketone bodies to levels significantly above the norm achieved with standard diets. Example(s) of these ketone body markers include betahydroxybutyrate, acetoacetate, and acetone.

Brief Summary Text (15):

Such a ketotic state inducing diet provides a nutritious maintenance diet to a dog or a cat with the benefit of altering the metabolism of the animal to attain the production of higher quantities of ketone bodies. The quantities of the significant components for the dog diet, all measured as wt. % of the diet and on a dry matter basis are about 0 to about 20 wt % of carbohydrates as nitrogen free extract, preferably 0 to about 10 wt %; about 25 to about 70 wt % of protein, preferably about 25 to about 40 wt %; and about 25 to about 70 wt % of fat, preferably about 30 to about 60 wt %.

Brief Summary Text (16):

The quantities of the significant components for the cat diet, all measured as wt % of the diet and on a dry matter basis are about 0 to about 20 wt % of carbohydrates as nitrogen free extract, preferably 0 to about 10 wt %; about 25 to about 70 wt % of protein, preferably about 30 to about 60 wt %; and about 20 to about 70 wt % of fat, preferably about 30 to about 60 wt %. Additionally, each diet will contain sufficient minerals and vitamins to avoid nutritional deficiencies.

Brief Summary Text (17):

The diet-induced state of ketosis can be useful in the treatment of certain conditions, which are affected by this altered metabolism. Examples of such conditions include but are not limited to seizures, for example, seizures accompanying idiopathic epilepsy particularly in dogs; weight regulation such as weight loss, gain, or maintenance; behavior problems, for example aggression, obsessive-compulsive disorder, and separation anxiety; muscle metabolism causing weakness or fatigue; carbohydrate intolerance (high or low blood sugar) for example, manifested by disorders of insulin secretion or insulin deficiency such as type II diabetes, exercise ability as shown by increased performance; and suboptimal exercise tolerance, for example myopathies and fatigue.

Detailed Description Text (9):

One composition of the new diet comprises fat, protein, supplemental minerals and vitamins, without any digestible carbohydrates. A small amount of fiber is added to maintain stool consistency. The diet is formulated to meet the AAFCO recommendations for all nutrients. A standard pet food diet would consist of the above constituents but also include 30-60% digestible carbohydrates in addition to fat, protein, minerals and vitamins in AAFCO recommended levels.

Detailed Description Text (15):

32 obese, adult, cats were tested in a repeated measures design to assess the effect of diet on ketone body production (ketosis) and weight loss.

Detailed Description Text (21):

Cats fed the ketogenic diet had a significantly higher amount of ketosis during both the ad libitum ($P<0.001$) and feed restricted periods ($P<0.0001$) compared to the cats on a feline maintenance diet during the prefeeding period. In addition, the cats fed ketogenic diet had significantly higher amounts of ketosis compared to the standard

weight-reduction diet during both periods as well ($P<0.02$). The standard weight-reduction diet did achieve a significant degree of ketosis in the limit-fed period but not during the ad libitum-fed period ($P=0.15$) as compared to prefeeding values.

Detailed Description Text (23):

Cats fed either diet during either period achieved a significant amount of weight loss compared to the prefeeding period. There was no significant difference between diets during the ad libitum feeding period but the ketogenic diet produced a significantly greater weight loss during the limit fed period ($P<0.04$).

Detailed Description Text (27):

Feeding a high fat, low carbohydrate diet to cats resulted in attainment of a ketotic state, weight loss, and normalization of blood glucose concentrations in obese, adult cats. The ketogenic diet demonstrated comparable improvement in glucose regulation to that previously reported for the weight-loss diet. The ketosis attained was significantly greater than when similar cats were placed on a standard weight reduction diet. In addition, the weight loss attained was similar to that in cats fed a standard weight control diet formulated for cats. No adverse effects of diet were noted in this experimental design. The ketogenic diet demonstrated comparable improvement in glucose regulation in comparison to the results previously reported from use of the standard weight loss diet.

Detailed Description Paragraph Table (1):

DIET COMPOSITION-STUDY 1 ORDINARY CANINE COMPONENT.^{sup.1} DIET (% WT).^{sup.2} KETOGENIC DIET.^{sup.2} Moisture 12.1 3.7 Protein 24.9 26.5 Fat 15.4 56.6 NFE 53.2 5.8 Crude Fiber 1.7 3.5 Ash 4.7 7.4 .^{sup.1} Diets include minerals and vitamins sufficient to meet daily requirements. .^{sup.2} All wt % is based on dry matter except moisture, which is % as fed.

Detailed Description Paragraph Table (2):

COMPOSITION OF THE DIET (AS FED BASIS) Weight Constituent Ketogenic Diet Reducing Diet
Moisture 75% 78% (max) Protein 9.7% 10.4% Crude Fiber 0.5% 3.1% Crude Fat 12% 4.2%
Minerals and vitamins sufficient to meet daily requirements

Detailed Description Paragraph Table (3):

BETA-HYDROXYBUTYRATE LEVEL (mg/dl) End Period 1/Start Diet Pre Period 2 End Period 2
Weight reduction diet 0.39 .+-. 0.33 1.06 .+-. 0.33 2.1 .+-. 0.33 Ketogenic diet 0.31
.+-. 0.33 2.64 .+-. 0.33 3.2 .+-. 0.33

Detailed Description Paragraph Table (4):

BODY MASS OF CAT (kg) End Period 1/Start Diet Pre Period 2 End Period 2 Weight
reduction diet 6.3 .+-. .08 6 .+-. .08 5.5 .+-. .08 Ketogenic diet 6.1 .+-. .08 5.8
.+-. .08 5.3 .+-. .08

Detailed Description Paragraph Table (5):

BLOOD GLUCOSE (mg/dl) End Period 1/Start Diet Pre Period 2 End Period 2 Weight
reduction 112.5 .+-. 4.7 103 .+-. 4.7 106 .+-. 4.7 diet Ketogenic diet 126 .+-. 4.7
108 .+-. 4.7 104 .+-. 4.9

Other Reference Publication (8):

Appleton DB, De vivio DC. An animal model for the ketogenic diet. Electroconvulsive threshold and biochemical alterations consequent upon high-fat diet. Epilipsia 1974; 15:211-227.

Other Reference Publication (10):

De Bruijne JJ. Biochemical observations during total starvation in dogs. International Journal of Obesity (1979) 3:239-247.

Other Reference Publication (11):

De Bruijne JJ, Altszuler N, Hampshire J, Vasser TJ, Hackeng WHL. Fat Mobilization and Plasma Hormone Levels in Fasted Dogs. Metabolism, vol. 30, No. , (Feb. 1981).

Other Reference Publication (12):

Hematological and metabolic responses to training in racing sled dogs fed diets

containing medium, low, or zero carbohydrate. DS Kronfeld et al., Am. Journ. of Clin. Nutrition, 30, 3, pp. 419-430 1977.

Other Reference Publication (13):

Isoenergetic substitution of dietary fat (beef tallow) for carbohydrates (cooked corn starch plus dextrin) does not affect magnesium absorption in cats. AC Beynen, J. Anim. Physiol. and Anim. Nutr., 72, 4/5 (1994) pp. 176-183.

Other Reference Publication (15):

Effects of Dietary Carbohydrate, Fat and Protein on Growth, Body Composition and Blood Metabolite Levels in the Dog. D. R. Romos et al., J. of Nutrition, vol. 106, No. 10, 1976, pp. 1452-1464.

Other Reference Publication (16):

Ketogenic diet reduces spontaneous seizures and mossy fiber sprouting in the kainic acid model. AB Muller-Schwarz et al., Neuroreport, vol. 10, No. 7, 1999, pp. 1517-1522.

Other Reference Publication (17):

Macronutrient Intake and Obesity, JW Daily et al., J. Food Sci, Nutr., vol. 5, No. 1, pp. 58-64.

CLAIMS:

1. A method for inducing a state of ketosis in a canine which comprises feeding to a canine in need of such ketosis on a regular basis a diet comprising carbohydrate measured as nitrogen free extract of about 0 to about 20 wt. % of the diet, protein of about 25 to about 70 wt. % of the diet, and fat of about 20 wt. % to about 70 wt. % of the diet on a dry matter basis.
2. The method of claim 1 wherein carbohydrate is from 0 to about 10 wt. % protein is about 25 to about 40 wt. % and fat is about 30 to about 60 wt. %.
3. A method for managing a medical condition or behavior condition selected from the group consisting of seizures, body weight regulation, aggression, obsessive compulsive disorder, separation anxiety, muscle metabolism causing weakness or fatigue, carbohydrate intolerance, disorders of insulin secretion or deficiency, and a combination of any of these conditions in a canine in need of such management which comprises feeding to said canine on a regular basis the diet of claim 1.
10. The method of claim 3 wherein the condition is carbohydrate intolerance.